Remarks/Arguments

Applicants have received and reviewed the Final Office Action mailed October 19, 2009. Currently, claims 17, 19, 39-40, 42-58, 60-61, and 63 are pending, of which all stand finally rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections - 35 USC §103

On page 2 of the Final Office Action, claims 17, 19, 39, 40, 42-56, 61, and 63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi et al. (U.S. Patent No. 6,325,826) in view of Marotta et al. (U.S. Patent No. 6,261,305), and further in view of Crocker et al. (U.S. Patent No. 5,843,116). After careful review, Applicants respectfully traverse the rejection.

Turning to claim 17, which recites:

> 17. (Previously Presented) A system comprising:
> only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a predetermined bulge region configured to protrude radially outward from the body region when expanded, the predetermined bulge region is positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region, wherein the predetermined bulge region is configured to have different pressure and/or inflation characteristics than the elongate body region; and
> a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, each of the moveable members being moveable independent of the other moveable members, the stent body being expandable from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body, in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and aligned with the predetermined bulge region of the single balloon, and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall by the expansion of the predetermined bulge region of the single balloon to form a scaffold, the scaffold defining a side opening in the stent wall.

Nothing in Vardi et al., Marotta et al., or Crocker et al., either alone or in combination, appear to disclose many elements of claim 17, including for example, "the predetermined bulge region is

positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region". In the Office Action, the rejection appears to rely on Marotta et al. and Crocker et al. as teaching or suggesting these elements. Applicants respectfully disagree.

Marotta et al. appear to disclose an endovascular prosthesis having a leaf portion that moves away from the tubular body of the prosthesis as the body is flexed upon navigation into a secondary artery. When the endovascular prosthesis in positioned in the correct position in an artery, a balloon appears to be expanded thereby exerting radially outward forces on the body, such that the body is urged against the wall of the artery. As expansion of the balloon continues, a portion of the balloon urges against the leaf portion urging the leaf portion against the wall of the secondary artery in a manner which results in blocking of the opening of the aneurysm. However, nothing in Marotta et al. appear to teach or suggest a balloon arrangement including a predetermined bulge region positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region.

Under the "Response to Arguments" heading and with reference to Marotta et al., the Final Office Action asserts that "[t]he bulge region is considered 'predetermined' and located at a 'predetermined' location around a circumference of the body region in that it is predetermined the bulge region occurs at the location of the movable member". Applicants respectfully disagree and submit that the bulge region merely occurring at the location of the moveable member is not the claimed predetermined bulge region of a balloon. Merely disclosing that any portion of the balloon which so happens to be aligned with the leaf portion is clearly not a predetermined region of the balloon. As such, nothing in Marotta et al. appears to disclose a single balloon having a predetermined bulge region "at a predetermined location around a circumference of the body region" and "configured to have different pressure and/or inflation characteristics than the elongate body region", as recited in claim 17.

Crocker et al. appear to disclose a focal balloon having at least one reference zone and a focal zone. In one embodiment, Crocker et al. appear to disclose the reference zone and the focal zone are inflatable to a first generally cylindrical profile at a first pressure and, at a second greater pressure, the focal zone expands to a second, greater diameter while the reference zone

remains substantially at the first diameter. In an alternative embodiment, the focal zone and reference zone are inflatable to their respective predetermined diameters at the inflation pressure. As illustrated in Figures 2 and 3 of Crocker et al., balloon 18 appears to include an inner balloon 36 disposed coaxially within an outer balloon 38. A substantially nondistensible expansion limiting band 40 is disposed between the balloons 36 and 38 adjacent to a proximal annular shoulder 42, to limit the radial expansion of the balloon 18. Similarly, a distal expansion limiting band 44 is disposed between the inner balloon 36 and outer balloon 38 adjacent a distal annular shoulder 46. Notably, expansion limiting bands 40 and 44 appear to comprise a tubular section of polyester, each having an axial length of about 5 mm, a diameter of about 2.5 mm and a wall thickness of about 0.0003 inches. Crocker et al. also appears to disclose that, in place of bands 40 and 44, the balloon can be provided with zones of differing wall thickness, or zones having different levels of cross linking. In any event, the thickness of the balloon in the focal zones appear to be greater than the thickness of the balloon in the focal zone, either through the use of a band or increased wall thickness. Further, Crocker et al. appears to disclose the use of a single layer balloon having varying zones of wall thickness. (See, for example, balloon 60 of Figures 6 and 7). In any event, the reference zones and the focal zones appear to be annular shaped about the balloon. Nothing in Crocker et al. appear to teach or suggest a balloon arrangement including a predetermined bulge region positioned at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region.

Further, nothing in Vardi et al. appears to remedy the noted shortcomings of Marotta et al. and Crocker et al. As such, nothing in Marotta et al., Crocker et al., or Vardi et al. appear to disclose "the predetermined bulge region is positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region", as recited in claim 17.

The Final Office Action states "it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Crocker to the balloon of Vardi and Marotta would have yielded predictable results and resulted in an improved system". As such, the Final Office Action appears to be applying the rationale of "Applying a Known Technique to a Known

Device (Method, or Product) Ready for Improvement To Yield Predictable Results" for establishing a *prima facie* case of obviousness, MPEP § 2143 (D) states:

> To reject a claim based on this rationale, Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:
>
> (1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement;"
>
> (2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product);
>
> (3) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and
>
> (4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.
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> The rationale to support a conclusion that the claim would have been obvious is that a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device (method, or product) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

With regards to factual inquiry (2), the known technique taught by Crocker et al. appears to be modifying a balloon to include a reference zone and a focal zone, wherein the reference zone includes a band of material or a band of increased wall thickness. As such, applying this "known technique" to the balloon of Vardi et al. would appear to result in a balloon having a band (i.e. around the entire circumference of the balloon) of increased wall thickness. Clearly, this would not result in the claimed device, namely, a balloon that includes a predetermined bulge region, "the predetermined bulge region is positioned at a location between a proximal end and a distal end of the body region and at a predetermined location around a circumference of the body region that extends less than the entire circumference of the body region", as recited in claim 17. Further, nothing in Marotta et al., which appears to disclose a balloon having a constant wall thickness, appears to teach or suggest any known technique to remedy the noted shortcomings of

Vardi et al. and Crocker et al. As such, there is no finding that the prior art contained a known technique that is applicable to the base device (factual inquiry 2) and, therefore, there cannot be a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system (factual inquiry 3) at least not an improves system as in claim 17. Thus, all of the findings cannot be made and, hence, the current rational used for the rejection is clear error and cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill. Therefore, for at least these reasons, claim 17 is believed to be patentable over Vardi et al., Marotta et al., and Crocker et al. For similar reasons and others, claims 19, 39-40, and 42-46, which depend from claim 17 and include additional distinguishing features, are believed to be patentable over Vardi et al., Marotta et al., and Crocker et al.

Turning now to claim 47, which recites:

> 47. (Previously Presented) A catheter system comprising:
>
> a catheter having a balloon arrangement, the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded, the bulge portion being positioned at a location between a proximal end and a distal end of the body region and positioned at a predetermined circumferential location around a circumference of the body region, the bulge portion extending around less than an entire circumference of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region; and
>
> a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, at least one of the moveable members being separate from the other moveable members, the stent wall being expandable from an unexpanded condition to an expanded condition by expansion of the body portion of the balloon arrangement, and the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent, wherein the bulge portion is positioned within the circumferential plane prior to expansion of the bulge portion, and after expansion of the bulge portion a portion of the bulge portion extends radially through the side opening outside the circumferential plane.

Nothing in Vardi et al., Marotta et al., and Crocker et al. appear to disclose many elements of claim 47, including for example, "the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded, the bulge portion being positioned at a location between a proximal end and a distal end of the body region and positioned at a predetermined circumferential location around a circumference of the body region, the bulge portion extending around less than an entire circumference of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region". Therefore, for similar reasons discussed above, as well as others, claim 47 is believed to be patentable over Vardi et al., Marotta et al., and Crocker et al. For similar reasons and others, claims 48-56, which depend from claim 47 and include additional distinguishing features, are believed to be patentable over Vardi et al., Marotta et al., and Crocker et al.

Turning now to claim 61, which recites:

> 61. (Previously Presented) A catheter system, comprising:
>
> only a single catheter, the single catheter having only a single balloon, the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a predefined bulge region configured to protrude radially outward from the body region when expanded, the predefined bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the predefined bulge region extending less than the entire circumference of the body region; and
>
> a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall and movable between an unexpanded position within the circumferential plane and an expanded position extending radially outward from the circumferential plane to define an aperture in the circumferential wall, the single balloon extending within the stent body from at least a distal end to at least a proximal end of the stent wall, the stent wall being expandable by expansion of the body region of the single balloon and the movable members being expandable by expansion of the predefined bulge region of the single balloon, wherein a first moveable member extends radially outward at a location distal of the aperture in the circumferential wall and a second moveable member extends radially outward at a location proximal of the aperture.

Nothing in Vardi et al., Marotta et al., and Crocker et al. appear to disclose many elements of claim 61, including for example, "the single catheter being adapted for insertion into a body vessel and advancement to a vessel bifurcation site, wherein the single balloon includes an elongate body region and a predefined bulge region configured to protrude radially outward from the body region when expanded, the predefined bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the predefined bulge region extending less than the entire circumference of the body region". Therefore, for similar reasons discussed above, as well as others, claim 61 is believed to be patentable over Vardi et al., Marotta et al., and Crocker et al.

Turning now to claim 63, which recites:

> 63. (Previously Presented)A catheter system for treating a bifurcated vessel, the catheter system comprising:
>
> a stent including a substantially tubular stent body having an open proximal end and an open distal end, wherein a portion of the stent body intermediate the open proximal end and open distal end includes a plurality of movable members configured to move between an unexpanded position and an expanded position, wherein when in the expanded condition, the plurality of moveable member extend radially outward from stent body to define an aperture; and
>
> an inflatable balloon, the inflatable balloon including an elongate body region having a bulge region configured to protrude radially outward from the body region when inflated, wherein the bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the bulge region extending less than the entire circumference of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region;
>
> wherein the stent is disposed about the balloon such that the bulge region of the balloon is aligned with the plurality of movable members of the stent, wherein the elongate body region of the balloon is configured to expand the tubular stent body when inflated, and the bulge region of the balloon is configured to move the plurality of movable member from the unexpanded position to the expanded position when inflated.

Nothing in Vardi et al., Marotta et al., and Crocker et al. appear to disclose many elements of claim 63, including for example, "an inflatable balloon, the inflatable balloon including an

elongate body region having a bulge region configured to protrude radially outward from the body region when inflated, wherein the bulge region is positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location around a circumference of the body region, the bulge region extending less than the entire circumference of the body region, wherein the elongate body portion has a first wall thickness and the bulge region has a second wall thickness different than the first wall thickness so that the bulge region has different inflation characteristics than the elongate body region". Therefore, for similar reasons discussed above, as well as others, claim 63 is believed to be patentable over Vardi et al., Marotta et al., and Crocker et al.

On page 4 of the Final Office Action, claims 57, 58, and 60 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (U.S. Patent No. 6,325,826) view of Marotta et al. (U.S. Patent No. 6,261,305). After careful review, Applicants respectfully traverse the rejection.

Turning to claim 57, which recites:

> 57. (Previously Presented) A catheter system comprising:
> a catheter having a balloon arrangement, the balloon arrangement including an elongate body portion; and
> a bifurcation stent including a stent body having a substantially tubular stent wall defining a circumferential plane, and a plurality of movable members engaged to the stent wall, the movable members configured as self expandable structures that move from an unexpanded position retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall, wherein expansion of the stent wall causes the movable members to move from the unexpanded position to the expanded position, at least a portion of the moveable members expanding towards a proximal end of the stent body and at least a portion of the moveable members expanding towards a distal end of the stent body;
> wherein the balloon arrangement further includes a predetermined bulge portion configured to extend radially outward from the elongate body portion when inflated, the predetermined bulge portion being positioned at a location between a proximal end and a distal end of the body region and extending around less than an entire circumference of the body portion, the stent positioned relative to the elongate balloon to position the movable members in axial and radial alignment with the predetermined bulge portion.

With this Amendment, claim 57 has been amended to include elements of claim 59, now canceled. Nothing in Vardi et al. or Marotta et al. appear to disclose many elements of claim 57, including for example, "wherein expansion of the stent wall causes the movable members to

move from the unexpanded position to the expanded position" or "wherein the balloon arrangement further includes a predetermined bulge portion configured to extend radially outward from the elongate body portion when inflated, the predetermined bulge portion being positioned at a location between a proximal end and a distal end of the body region and extending around less than an entire circumference of the body portion". Therefore, for at least these reasons, claim 57 is believed to be patentable over Vardi et al. in view of Marotta et al. For similar reasons and others, claims 58 and 60, which depend from claim 57 and include additional distinguishing features, are believed to be patentable over Vardi et al. and Marotta et al.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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